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Administrator

December 6, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket 97N-484S

To Whom It May Concern:

This correspondence is to publically comment on the proposal to regulate some types of allograft material as medical devices. As a practitioner who uses these products on a regular basis, I feel that FDA involvement in the above aforementioned area is not appropriate, and is not supported. Allograft bone usage has been well established, and therefore I do not feel that the FDA has any jurisdiction and should not be attempting to impose requirements for clinical trials and lengthy regulatory documentation. I feel that doing such would be a detriment to patient care if it effectively stops the product from being available on a user friendly basis.

I think if the FDA's intention is to oversee manufacturing and quality assurance, that may be a different issue, but by no means do I think the FDA should be imposing requirements for lengthy clinical trials and documentation for material which has been implanted for many, many years.

Sincerely,

Patrick S. McNulty, M.D.

Charter Diplomate, American Board of Spine Surgery
Diplomate, American Board of Orthopedic Surgery
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PSM:skp

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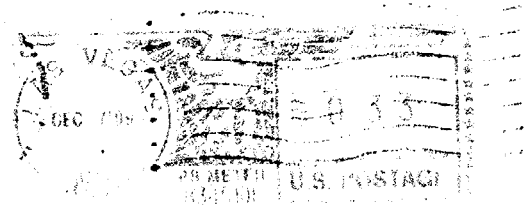

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